Message

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Sent: 11/8/2011 2:40:49 PM
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Subject: NEWS UPDATES: NTP Proposes New Process For Industry-Challenged Carcinogens Report (Risk Policy Report)

NTP Proposes New Process For Industry-Challenged Carcinogens Report

Posted: November 7, 2011

The National Toxicology Program (NTP) is proposing a new process for the drafting of its Report on Carcinogens (RoC), following strident industry opposition to the most recent report that mirrors industry's criticisms of EPA chemical risk assessments.

But the new approach is still drawing industry criticism, with the American Chemistry Council (ACC), a chemical industry association, urging NTP in a Nov. 3 letter to extend and reconfigure the public comment period on the new process for the congressionally mandated biennial report.

Congress first ordered NTP to produce the RoC in 1978, according to the program's website. The documents provide information on chemicals that NTP deems carcinogenic or those it reasonably anticipates to be human carcinogens, along with people's potential for exposure to them, whether they are genotoxic and how they cause cancer.

NTP is now proposing a new four-step process for creating future RoC reports, following controversy over its most recently released RoC. The 12th RoC, released last June, included both formaldehyde and styrene -- which were challenged by industry.

ACC and other critics protested NTP's listing of formaldehyde as a leukemogen -- as EPA's Integrated Risk Information System (IRIS) assessment also did. EPA's conclusions, however, were challenged by a National Academy of Sciences (NAS) panel that reviewed its assessment, and questioned the sufficiency of the evidence EPA presented in an April 2011 report. Industry then criticized NTP for releasing the RoC with similar views and information on formaldehyde (*Risk Policy Report*, June 14). And, the Styrene Information and Research Center has sued the Department of Health & Human Services (HHS) -- where NTP is housed -- over its listing of styrene as a human carcinogen.

NTP explains that its proposed four-part process includes the nomination and selection of candidate substances to be included in the next RoC; "a scientific evaluation of the substances"; public release of the draft RoC for comment and peer review; and HHS approval of the final RoC before its publication. The program lays out its proposal in a document announced in an Oct. 31 *Federal Register* notice. *Relevant documents are available on InsideEPA.com.* (*Doc ID: 2381304*)

NTP's proposed new process starts with the program soliciting submissions from the public. NTP staff will evaluate each of the nominated substances to "determine whether there is sufficient information on exposure and carcinogenicity to justify its formal evaluation and consideration for the RoC." NTP staff then share its conclusions with its "agency partners," including EPA, the Consumer Product Safety Commission, Department of Defense, Food & Drug Administration, National Cancer Institute, the Agency for Toxic Substances & Disease Registry, the National Institute of Environmental Health Sciences, the National Institute for Occupational Safety & Health and the Occupational Safety & Health Administration.

NTP staff then prepare a "concept document" on all substances proposed for evaluation, including "the rationale for the substance's review" and "the proposed approach for development of the cancer evaluation component of the draft RoC Monograph on the substance." Next, NTP solicits public comments on the document's advice from its Board of Scientific Counselors (BSC). From this input, the NTP director determines which substances should be included in an RoC.

NTP staff then prepare draft monographs for each substance. Each is released for public comment and peer review by "an external advisory group." Using these reports, the monographs are finalized. Every two years, NTP then seeks "consultation" from its executive committee of sister agency representatives on its new monographs before they are submitted to the HHS secretary for review and approval of inclusion in a RoC.

NTP's *Federal Register* notice indicates that NTP will accept public comment through Nov. 30 on the proposed process, including a listening session webinar Nov. 29. But ACC argues that NTP's process for soliciting comment is inadequate, and calls for the program to extend the comment time.

"We are pleased that [NTP] recognizes the need for improvements in the [RoC], and appreciate NTP's interest in obtaining stakeholder input," writes Cal Dooley, ACC's president and CEO in a Nov. 3 letter to NTP Director Linda Birnbaum. "NTP's timelines are not adequate to obtain, review and respond to meaningful public input. In ACC's view, this approach is not consistent with President Obama's goals for transparency and scientific integrity."

Dooley urges Birnbaum to extend the written comment period to 90 days, delay the webinar by two or three weeks and add an in-person meeting. Dooley also asks that the meeting be structured "as a dialogue, in which NTP staff actively engage in discussions with stakeholders on the substantive issues, rather than as a one-way discourse," and that after the meeting NTP staff "analyze and respond to public comments, providing a written record of NTP's rationale for accepting or rejecting comments and for making specified policy choices, and publish a revised draft process clearly noting what changes have been made."

Lastly, Dooley urges Birnbaum to "submit the revised draft RoC process, including the improved scientific analysis procedures, for independent scientific peer review by the [NAS]."

ACC's criticisms and requests are similar to those they and others in industry have made to EPA regarding the drafting of its IRIS assessments. At ACC's request, EPA a few years ago added a step in its IRIS process where it holds a listening session during the public comment period on each draft assessment. Industry and other critics are also urging EPA to submit more of its draft IRIS assessments to NAS for review, instead of having the documents reviewed by EPA's Science Advisory Board or contracted external experts. Both alternatives are considered lower levels of scrutiny.

"As you are aware, many questions have arisen regarding the scientific evaluation and peer review processes used to develop the RoC," Dooley writes. "The striking differences between the [NAS] peer review report of the draft [IRIS] assessment and the NTP findings regarding the causal relationship between formaldehyde exposure and leukemia is but one example of the need for NTP to substantively improve the RoC process."

This review will be the second overhaul of the RoC process since 2004, when "NTP revised the RoC review process for the 12th RoC to enhance the scientific development of the report and address guidance in the [White House] Office of Management and Budget (OMB) Peer Review Bulletin," according to NTP's website. That revision added two new elements to the RoC process: a public peer review by experts of NTP's draft background documents and public peer review by NTP's BSC of draft substance profiles.

During remarks at the Society of Toxicology annual meeting in Washington, DC, last March, Birnbaum said, "We are supposed to release the RoC every two years. The last one was released in 2005; there was a lot of back and forth with the [OMB]."

"They finally approved our new [RoC] review process in 2008" (*Risk Policy Report*, March 15). -- *Maria Hegstad*

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